

15-EH-01 (Revised 12/4/15)

Committee: Environmental Health

Title: Public Health Reporting and National Notification for Elevated Blood Lead Levels

I. Statement of the Problem

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. (1) The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support “automated case reporting from electronic health records or other clinical care information systems.” In July 2008, CSTE identified sixty-eight conditions with existing Position Statements that warranted inclusion on the official list, including elevated blood lead levels, each of which requires a standardized reporting definition to support the surveillance case definition.

CSTE initially adopted two position statements on public health surveillance for lead exposure in 1995: “Adding Elevated Blood Lead Levels Among Young Children as a Condition Reportable to the National Public Health Surveillance System” and “Adding Elevated Blood Lead Levels Among Adults as a Condition Reportable to the National Public Health Surveillance System.” (2) (3) The latter was revised in 1999 and retitled “Surveillance Case Definition for Adult Blood Lead Levels to be Reported to the National Public Health Surveillance System.” (4) CSTE approved the position statement “Public Health Reporting and National Notification for Elevated Blood Lead Levels” in 2009. (5) Subsequently, national consensus has emerged that the definition of “elevated” should be reduced from 10 µg/dL to 5 µg/dL or greater in adults and children. CDC and CSTE recognize that adverse health effects can occur at blood lead levels lower than 10 µg/dL.

II. Background and Justification

Inorganic lead is a bluish gray metal that has been used since ancient times because of its useful properties, such as low melting point, pliability, and resistance to corrosion. The ancient Romans and Greeks first discovered its toxic effects. Lead is widespread in the U.S. environment because of the extensive use of lead compounds in industry, gasoline, and paints during the past century. Environmental and biological measures of lead have been decreasing due to the elimination or restriction of lead in consumer products including gasoline and household paint. Lead is not an essential element nor does it serve any useful purpose in the body. It adversely affects multiple organ systems and can cause permanent damage. Research shows that lead has adverse health effects, including neurotoxicity and adverse renal and reproductive effects at much lower levels than once believed safe.

Human exposure to inorganic lead occurs when dust and fumes are inhaled and when lead is ingested in food or water. Lead on surfaces such as counters, floors, window sills, clothing and shoes may be transferred to hands and ingested when hands are placed in the mouth (e.g., by toddlers) or by contamination of food because of inadequate hand washing. Lead absorbed from the respiratory and digestive systems into the blood is distributed to tissues throughout the body.

More than 90 percent of total body lead content eventually accumulates in the bones, where it has a half-life of years to decades. Lead stored in bones continues to be released, via the bloodstream, to tissues throughout the body long after the external environmental exposure has ceased.

There are several biological measures of lead exposure. The best method for monitoring biological exposure to lead is measurement of the blood lead level (BLL) in whole blood. Blood lead levels provide a readily available, standardized, and relatively low cost method to assess lead exposure. The frequency and severity of symptoms associated with lead exposure generally increase as the BLL increases although there is much individual variability. The half-life of lead in blood is about five weeks.

Elevation of protoporphyrin (free or zinc protoporphyrin) concentration in red blood cells can indicate inhibition of heme synthesis by lead, but it is an insensitive biomarker of lead exposures in individuals with blood lead concentrations below 25 µg/dL. Additionally, there are other causes (e.g., iron-deficiency anemia and inflammatory conditions) of elevated protoporphyrin levels. Lead concentrations in urine, teeth, and hair have been used as biological indicators of current or past lead exposure. Urinary lead is less validated than blood lead as a biomarker of external lead exposure, while laboratory analysis for lead in hair is not standardized. For these reasons, there is rarely any value in measuring lead in urine or hair. Measurement of bone lead levels, via K-shell X-ray fluorescence (K-XRF), provides an accurate method for determining cumulative lead exposure in bone and the total body burden of lead. Currently, because the number of K-XRF machines available in the United States for use for bone lead testing is less than ten, K-XRF remains a research tool.

An elevated [BLL](#) was defined by CSTE and CDC in 2009 as 10 µg/dL or greater for children and adults. (5) Recent research has documented adverse health effects at BLLs well below these defined levels. (6) In 2012, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommended that a BLL of 5 µg/dL or greater be defined as elevated, and CDC and states have concurred with this definition. This reference range value was based on the 97.5th percentile of the BLL distribution among children 1–5 years old in the United States using data generated by the 2007-2010 National Health and Nutrition Examination Survey (NHANES). The recommendation was based on the compelling evidence that low BLLs are associated with IQ deficits, attention-related behaviors, and poor academic achievement. The ACCLPP noted that “...the absence of an identified BLL without deleterious effects, combined with the evidence that these effects appear to be irreversible, underscores the critical importance of primary prevention.” (7) CDC expects to update the reference range value every four years using the two most recent NHANES surveys. (8)

Likewise there has been increasing evidence of the toxicity of lead for adults at low doses and its association with hypertension, adverse effects on renal function, cognitive dysfunction, and adverse female reproductive outcomes. (6) A 2013 CSTE publication recommended that individuals with BLLs of 5 µg/dL or greater be monitored for elevated BLL and that, if exposed in the workplace, be considered for removal from exposure based on pregnancy or certain medical

conditions (E.g. chronic renal dysfunction and neurological disease). “Recent evidence suggests that chronic low-level lead exposure has adverse health effects in adults and no blood lead threshold level for these effects has been identified.” (9) These guidelines were adopted by the Association of Occupational and Environmental Clinics. (10) The lead burden in the U.S. adult population has been steadily declining as evidenced by the NHANES Fourth National Report on Human Exposure to Environmental Chemicals, which estimated that the mean (geometric) blood lead concentration in 2011-12 was 1.09 µg/dL for the U.S. population aged 20 year and older, and 95% having a BLL of 3.36 or less. (11) However, adult lead exposures in the United States continue to occur at unacceptable levels; in 2012, thirty-eight State ABLES Programs submitted data on 27,529 adults with BLLs ≥10 µg/dL yielding a national prevalence rate of 22.5 adults /100,000 employed.(12) Based on scientific research and public health concerns, this position statement recommends lowering the definition of elevated blood lead in adults from 10 to 5 µg/dL.

The leading source of elevated blood lead in children is exposure to lead-based paint in houses built before 1978. The leading cause in adults is occupational exposure to lead. (Around 95 % of blood lead levels ≥25 µg/dL are from occupational exposure).(12,13) Other routes of lead exposure in children include pica behavior, mouthing of items containing lead, and contact with family members’ contaminated clothing. For adults, other sources of exposure include sport shooting, casting and reloading of bullets, use of lead-contaminated alternative medicines, and do-it-yourself renovation of homes built before 1978.

Some states require reporting of lead poisoning and/or elevated lead test results by health care providers. However, reporting of BLLs by clinical laboratories to state childhood and adult/occupational lead surveillance systems has been shown to be the most complete and effective reporting source. Surveillance built on laboratory reporting of BLL has led to a wide variety of public health prevention and intervention activities. Reporting of *all* BL test results by laboratories, which is required in many states, is essential for determining prevalence in the tested population.

The condition “Elevated Blood Lead” meets the following criteria for a nationally and standard notifiable condition, as specified in CSTE position statement 08-EC-02 (14) and 10-SI-02 (15):

- CDC requests standard notification of elevated BLLs to federal authorities.
- CDC has condition-specific policies and practices concerning the agency’s response to, and use of, notifications.

III. Statement of the desired action(s) to be taken

Summary: CSTE requests that CDC adopt the standardized definition for an elevated BLL presented below to facilitate timely, complete, and standardized local and national reporting of this condition. This definition includes a newly revised case definition for elevated BLL in children and adults and maintains the recommendation of 09-OH-02 that laboratories report *all* blood lead test results, not just those defined here as elevated.

1. Utilize standard sources (e.g. reporting*) for case ascertainment for elevated blood lead levels, as indicated in the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of elevated blood lead.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	x	
Laboratory reporting	x	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)		
Death certificates		
Hospital discharge or outpatient records		
Extracts from electronic medical records		
Telephone survey		
School-based survey		
Other _____		

2015 Template

2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for] and continue to include elevated blood lead levels on the *Nationally Notifiable Condition List*

- ☐ 2a. Immediately notifiable, extremely urgent (within 4 hours)
- ☐ 2b. Immediately notifiable, urgent (within 24 hours)
- X 2c. Routinely notifiable

CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make all blood lead laboratory test results reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.

3. CDC should publish data on BLL as appropriate in *MMWR* and other venues (see Section IX).

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined in this document.

Terminology:

* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health.

**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of elevated BLL to facilitate and evaluate their prevention and control.

V. Methods for Surveillance: Surveillance for elevated blood lead levels should use the recommended sources of data and the extent of coverage listed in Table III.

The primary source of data for BLLs is clinical laboratories because laboratory test results capture all results of all tests ordered by health care providers. Reporting from clinical laboratories is very complete, because almost all clinical laboratories have established infrastructure and/or automated electronic reporting systems in place for transmitting results of tests for *all* reportable conditions. Blood lead testing using “point-of-care” (POC) technologies¹ has become increasingly prevalent in physician office laboratories. Mandatory reporting of physician office-based laboratory lead test results generally falls under the same state statutes or regulations mandating clinical laboratory reporting. However, POC testing poses challenges to surveillance because many physician offices are not aware of the laboratory reporting requirement and/or do not have the technology to automate electronic laboratory reporting.

Reporting by health care providers who use external clinical laboratories for blood lead analysis is secondary to reporting by the laboratories, given the completeness of reporting by the laboratories, but it may be useful for capturing demographic and other information about patients that is not provided to the laboratory when the provider orders the blood lead test.

The completeness of testing of children depends on the state, with some states mandating universal testing and others only of certain populations. Blood lead testing of adults is required by federal and state Occupational Safety and Health laws and regulations for employees meeting certain criteria for potential exposure to lead; however compliance with this requirement may not be complete.

VI. Criteria for case identification

Note: “adult” is defined as an individual age 16 years and older. (13)

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

- Laboratories should report **ALL** BLLs to public health authorities.
- Health care providers should report elevated BLLs meeting either of the following criteria:

¹ Currently, the only FDA approved POC instrument is “LeadCare®II Blood Lead System” manufactured by Magellan Diagnostics. For more information see “*Guidelines for measuring lead in blood using point of care instruments*.” Advisory Committee on Childhood Lead Poisoning Prevention of the CDC. 10/14/2013. http://www.cdc.gov/nceh/lead/ACCLPP/20131024_POCGuidelines_final.pdf

- o A person < 16 years of age with a lead concentration in a capillary blood specimen $\geq 5 \mu\text{g/dL}$ ($0.24 \mu\text{mol/L}$).
- o A person of any age with a venous blood lead concentration, as determined by a CLIA-certified facility, $\geq 5 \mu\text{g/dL}$ ($0.24 \mu\text{mol/L}$).
- *Other recommended reporting procedures*
 - Reporting should be on-going and routine.
 - Frequency of reporting should follow the state health department's routine schedule.
 - Laboratory reporting should be electronic.

B. Table of criteria to determine whether a case should be reported to public health authorities

Note: Table VI-B-1 applies to criteria for laboratory reporting of all BLL results and Table VI-B-2 applies to clinician reporting of cases with elevated BLL.

Table VI-B-1. Criteria for laboratory reporting of BLL. Meeting the criteria listed under any single column of this table is sufficient to report a result.

Criterion	Reporting BLL condition subtypes			
	Child Capillary	Child Venous	Adult Capillary	Adult Venous
Person < 16 years of age	N	N		
Person ≥ 16 years of age			N	N
<i>Laboratory Findings</i>				
Any blood lead test result in a capillary blood specimen	N		N	
Any blood lead test in a venous blood specimen		N		N

Notes:

N = Necessary; this criterion in conjunction with all other "N" in the same column is required to report a result.

Table VI-B-2. Criteria for clinician reporting of a case of an elevated BLL. Meeting the criteria listed under any single column of this table is sufficient to report a case.

Criterion	Reporting BLL condition subtypes		
	Child Capillary	Child Venous	Adult Venous

Person < 16 years of age	N	N	
Person ≥ 16 years of age			N
<i>Laboratory Findings</i>			
lead concentration ≥5 µg/dL (0.24 µmol/L) in a capillary blood specimen	N		
lead concentration ≥5 µg/dL (0.24 µmol/L) in a venous blood specimen		N	N

Notes:

N = Necessary; this criterion in conjunction with all other “N” in the same column is required to report a case.

C. Disease-specific data elements

In addition to standard data elements to be included in the initial report (e.g. patient name, demographics, reporter name/address), disease-specific data elements to be included in the initial report are listed below.

For persons < 16 years of age:

Specimen type	Venous Capillary
Parent/guardian	Name Street address Second address line City State Zip code Phone

For persons ≥16 years of age:

Specimen type	Venous Capillary
Current Occupation	Job title
Current Employer	Name Street address Second address line City State

Zip code
Phone
Employer's industry type

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

Note: If specimen type is unknown it should be considered capillary for persons <16 years of age and venous for persons ≥16 years of age, for the purpose of case classification.

Elevated Blood Lead Levels Among Children

Laboratory criteria

Blood lead concentration, as determined by a CLIA-certified or CLIA-waived facility, ≥5 µg/dL (0.24 µmol/L) in a child (person < 16 years of age)

Case classification

Unconfirmed: a single capillary or unknown blood specimen with elevated lead concentration or two capillary blood specimens, drawn greater than 12 weeks apart, both with elevated lead concentration.

Confirmed: one venous blood specimen with elevated lead concentration, or two capillary blood specimens, drawn within 12 weeks of each other, both with elevated lead concentration.

Elevated Blood Lead Levels among Adults

Laboratory criteria

Blood lead concentration, as determined by a CLIA-certified facility, of ≥5 µg/dL (0.24 µmol/L) in an adult (person ≥16 years of age).

Case classification

Confirmed: one venous blood specimen with elevated lead concentration.

Comment

Elevated blood lead levels, as defined above, should be used as standard criteria for case classification for the purposes of surveillance but may not correspond to action levels determined by individual public health programs or by providers with respect to patient care. Note: For

medical management guidelines for lead-exposed adults please see guidelines from CSTE (9) and AOEC (10).

B. Classification Tables

Table VII-B. Criteria for defining a case of an elevated BLL. Meeting the criteria listed under any single column of this table is sufficient to classify a case, as indicated by the column's heading.

Criterion	Case Definition					
	Confirmed			Unconfirmed		
<i>Clinical Evidence</i>						
person < 16 years of age	N	N		N		N
person ≥ 16 years of age			N			
<i>Laboratory Evidence</i>						
lead concentration ≥5 µg/dL (0.24 µmol/L) in a single capillary blood specimen				N		
lead concentration ≥5 µg/dL (0.5 µmol/L) in a capillary blood specimen drawn within 12 weeks of another capillary blood specimen with a lead concentration ≥5 µg/dL (0.24 µmol/L)		N				
lead concentration ≥5 µg/dL (0.5 µmol/L) in a capillary blood specimen drawn more than 12 weeks after another capillary blood specimen with a lead concentration ≥5 µg/dL (0.24 µmol/L)						N
lead concentration ≥5 µg/dL (0.24 µmol/L) in a venous blood specimen	N		N			
<i>Criteria to distinguish a new case</i>						
Counted once per year, regardless of number of elevated BLL in same year.	N	N	N			

Notes:

Elevated BLL classification does not use any case classification categories other than “confirmed” and “unconfirmed.” The “unconfirmed” category identifies tested children with a potentially elevated BLL but where testing was inadequate to make that determination. N=Necessary; this criterion in conjunction with all other “Ns” in the same column is required to classify a case.

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

Expectations for sharing case data to CDC

- State and territorial health agencies will submit individual reports of all confirmed elevated BLLs in adults (≥ 16 years of age) to CDC at least once **a year**.
- State and territorial health agencies will submit individual reports of all confirmed elevated BLLs AND unconfirmed 5 to <10 $\mu\text{g}/\text{dL}$ BLLs in children (<16 years of age) to CDC **quarterly or as requested**.

Note: This Position Statement encourages notification of case data on all BLLs to CDC, regardless of whether they meet the definition of a confirmed, elevated BLL. However, this Position Statement recognizes that jurisdictions may not have the resources to collect and process all BLL laboratory reports, and thus at a minimum, jurisdictions should share case data on all confirmed cases with blood lead results of ≥ 5 $\mu\text{g}/\text{dL}$. In addition, jurisdictions should share data on unconfirmed cases with blood lead results of 5 to <10 $\mu\text{g}/\text{dL}$ in children.

Limitations on releasing case data

- CDC may release fully de-identified individual case data to appropriate non-CDC researchers or other government agencies through special-use agreements, as long as the data release does not compromise federal or state privacy or confidentiality policies or regulations, proprietary interests, national security interests, or law enforcement activities. Refer to the CDC-ATSDR data release guidelines on re-release of state-provided data (16,17) for further information.

Restrictions on printing counts of case data

- CDC will only publish data on confirmed cases of elevated BLLs ≥ 5 $\mu\text{g}/\text{dL}$ and unconfirmed cases 5 to <10 $\mu\text{g}/\text{dL}$ in children. Provisional data will not be used until verification procedures are complete.

Publications

- Data will be analyzed and findings will be disseminated through peer-reviewed publications, MMWR articles, at meetings, and the CDC web site, to guide intervention and prevention strategies. Data suppression in publications should comply with state requirements and CDC guidelines (16,17) to protect the confidentiality of personal identifying information.
 - o For adult blood lead data: A national summary aggregated de-identified data set will be made available to the public through the NIOSH/ABLES website, 18 months after the close of the calendar year.
 - o De-identified case data will be shared with the US Occupational Safety and Health Administration (OSHA) in the Department of Labor, which is the agency responsible for the federal regulation and enforcement of the OSHA Lead Standards 1910.1025 and 1926.62, to help target the National Emphasis Program on Lead.
 - o For child blood lead data, data will be made available on CDC websites by state and county. Data will also be used to generate analyses of temporal trends in blood lead levels and other studies.
- Analytic findings by CDC will be shared with state partners before the findings are submitted for peer review and before the findings are made publicly available.

X. References

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